

1. General

1.1. After notification of the following Berlin Cert GmbH general terms and conditions, the validity of which is accepted by Berlin Cert GmbH's contractual partner, the Parties will have concluded the contract based on these GTCs.

1.2. The following conditions apply to the agreed services, including provision of information, deliveries, and the like, as well as to supplementary services rendered in the context of implementing the contract, and other contractual supplementary obligations.

1.3. Any other general terms and conditions will not be a part of the contract, even if Berlin Cert GmbH does not explicitly reject them. They will not be tacitly acknowledged by Berlin Cert GmbH.

2. Scope of application

These GTCs in particular govern the implementation of tests, evaluation, certification, and inspections of management systems or medical devices with regard to safety, fitness for use, and quality on the basis of relevant standards and regulations, such as the Medical Devices Act, the EC Directive 93/42 / EEC, national, European, and international standards, and requirements that Berlin Cert GmbH has agreed upon with the Client.

Service fees will be charged for implementation of services referred to in these general terms and conditions, in accordance with Berlin Cert GmbH's valid list of fees or quote. All costs are subject to statutory value-added tax. Associated costs (transportation costs, travel expenses, etc.) are not included. All services offered by Berlin Cert GmbH are always subject to VAT, unless German tax law allows for exceptions.

If the Client cancels a contractual order ahead of schedule, a processing fee will still be payable, the amount of which will correspond to the work carried out up to this point. It will amount to at least € 150 for product tests and € 300 for certifications of quality management and quality assurance systems. Further work that we are not responsible for, for example as a result of changes to a device to be tested, its retrofitting or repair, etc., will be invoiced at € 175 per hour worked. Submitted documents will only be accepted in German or English.

These general terms and conditions apply to merchants within the meaning of Section 24 of the German General Terms and Conditions Act (§24 AGB-Gesetz), and to all legal persons within public law, and legal public bodies, unless otherwise expressly determined otherwise.

3. Scope of service / deadlines

3.1. Only written confirmation of Berlin Cert GmbH's quote, or written confirmation of contract conclusion between the contractual partners will be decisive for the scope of service.

Unless expressly agreed, Berlin Cert GmbH is not responsible for the testing or accuracy of the safety and security programs that underlie its tests and inspections.

3.4. The contractually agreed service deadlines and dates are based on estimates of the scope of work; therefore Berlin Cert GmbH's deadlines are not binding, unless their binding character has been expressly agreed in writing.

Binding dates begin with conclusion of the contract. Insofar as an advance payment has been agreed on, or advance Client services have been agreed on, the deadline period shall not commence until after reception of the advance payment or fulfilment of the advance services. The later point in time is always decisive. Berlin Cert GmbH will be in default if a delivery date or a delivery period (binding or not) is exceeded, or if deadlines are exceeded, if Berlin Cert GmbH is responsible for the delay in delivery. In the event of force majeure or other unforeseeable obstructions it is not responsible for, a delay in delivery will not obtain.

In addition to the delivery, the Client can only demand compensation for damage caused by delay if intent or gross negligence on behalf of Berlin Cert GmbH is proven. With regard to the service performance deadline, the client may only withdraw from the contract or demand damages instead of fulfilment in the event of service delay by Berlin Cert GmbH, or given impossibility of delivery that Berlin Cert GmbH is responsible for.

3.5. If the availability of test equipment between the contractual partner and Berlin Cert GmbH is agreed in writing by a certain date in the event of a contractual order, it is obliged to pay loss damages in accordance with the following scheme, provided that usage does not take place for reasons attributable to the contractual partner, and if alternate usage by Berlin Cert GmbH cannot be arranged.

3.6. Subject to the provisions in Section 3.7., schedule changes by the contractual partner are possible up to 7 business days prior to the agreed test date, without this leading to additional costs for the contractual partner. Given appointment cancellations at short notice, or postponements up to 3 working days before the test date, Berlin Cert GmbH reserves the right to invoice the contractual partner for 50% of the lost contractual order value (excluding ancillary expenses) as a compensation payment. At the end of the above-mentioned deadline periods the contractual partner is required to compensate the full value of the contract in postponements or rescheduling.

3.7. Should any cancellation fees arise from third parties due to rescheduling or postponements by the contractual partner, the later will bear these costs in full.

4. Obligations of the contractual partner

4.1. Berlin Cert GmbH's contractual partner warrants that all required supportive measures of its own or of its vicarious agents will be provided for Berlin Cert GmbH free of charge and on time. These cooperative actions must conform to the applicable standards, safety regulations (ISO, DIN, etc.) and correspond to accident prevention regulations.

4.2. Berlin Cert GmbH's contractual partner shall bear any additional costs resulting from the fact that work must be repeated or is late due to delay, incorrect or incomplete information, or improperly executed cooperative measures. By agreement, Berlin Cert GmbH is also entitled to invoice a binding fixed or maximum price, given this kind of additional work expenditure.

4.3. If the contractual partner discovers that the samples certified by Berlin Cert GmbH have been or could be the cause of personal injury, property, or other damages, it is obliged to immediately inform Berlin Cert GmbH of this in writing. In cases where the tests were carried out by another laboratory than Berlin Cert GmbH and its results have been used by Berlin Cert GmbH as basis for the certification of devices, the Berlin Cert GmbH contractual partner will immediately communicate in writing if it discovers that the results from the other testing laboratory underlying the certification are completely or partially invalid, void, or inconclusive.

4.4. The contractual partner undertakes to indemnify Berlin Cert GmbH, its directors, workforce, employees, officers, and vicarious agents against all costs and expenses of any kind on first request, which are directly caused by:

- a) any breach by the contractual partner of the provisions of these general terms and conditions, including non-compliance or omission of other requirements,
- b) any application of the device in a way that does not correspond with the requirements,
- c) any instance of subsequent auditing of devices certified as per these provisions,
- d) any event triggering damage that occurs during testing of the equipment, and
- e) every deliberate or inadvertent omission by the contractual partner, significant disclosures or other misinterpretations communicated in writing to Berlin Cert GmbH, insofar as the liabilities for losses, costs, damages, legal fees or other expenses were not caused by Berlin Cert GmbH's gross negligence or intentional behaviour via acts or omissions in the awarding of certifications.

4.5. The contractual partner undertakes not to disclose or reproduce in excerpts the work results of Berlin Cert GmbH, such as inspection reports and expert opinions, or the like, without the written permission of Berlin Cert GmbH. The contractual partner also undertakes not to quote or interpret the test results in an improper, falsified, or misleading manner.

5. Warranty / Liability

5.1. Berlin Cert GmbH's warranty only includes the expressly commissioned services. No warranty is undertaken for the correctness and functioning of an entire system which includes the inspected or tested parts, particularly for design, materials, and construction of the examined systems, insofar as these points are not expressly included in the contract. Even in the latter case, the warranty obligation and legal responsibility of the Client or device manufacturer will be neither restricted nor undertaken.

For services rendered by Berlin Cert GmbH, the Parties are in agreement that Berlin Cert GmbH is not liable for any particular outcome or for a certain result, and making decisions based on the services solely falls within the Client's risk and decision-making purview.

If defects occur within the warranty period Berlin Cert GmbH initially has the right to avail itself of supplementary performance. Berlin Cert GmbH can provide the supplementary performance by remedying the defect (repair) or by replacement (subsequent delivery). Only if supplementary performance is definitively and correctly rejected, is repeatedly not made within the prescribed period, or fails, does the Client have the right to demand a price reduction or cancellation of the contract as per the legal provisions. Other warranty rights are excluded.

The client has no right of rescission given only minor defects and non-conformities. If Berlin Cert GmbH is not responsible for a breach of obligation that has caused a defect, the Client is also not entitled to rescind the contract.

Typos, grammar errors, formatting of text, such as line breaks, fonts and font size, layout, and interpretable statements in test reports, are explicitly not to be considered in need of correction.

The Client must promptly provide notice of complaints in writing once they are determined, at the latest within a year after issuance of the report or certificate. A claim for damages in the absence of guaranteed characteristics remains unaffected.

All warranty claims are excluded if they are not asserted within one year after the transfer of risk (usually with handover).

5.2 For all damages - for whatever legal reason - Berlin Cert GmbH is only liable if legal representatives, vicarious agents, or Berlin Cert GmbH itself has caused these damages intentionally or through gross negligence, or if Berlin Cert GmbH, its representatives, or its vicarious agents have negligently breached an essential contractual obligation. Given breach of essential contractual obligations, Berlin Cert GmbH's liability will be limited to the contractually typical, foreseeable damages. Liability is excluded for indirect consequential damages, including contractually typical consequential damages.

These liability exclusions and limitations shall not apply to damages resulting from injury to persons or damages resulting from gross negligence by Berlin Cert GmbH, or that result from wilful gross neglect of duty by a legal representative or vicarious agents of Berlin Cert GmbH. These liability exclusions and limitations also do not apply to damages resulting from culpable violation of essential contractual rights and obligations within the meaning of § 307 para. 2 no. 2 BGB (German Civil Code).

The liability of Berlin Cert GmbH shall be limited to the insured sums of 2,500,000.00 EUR for damages to persons and property, and to 500,000.00 EUR for financial damages.

The Client must immediately inform Berlin Cert GmbH of complaints and damages in writing.

If claims for damages against Berlin Cert GmbH are excluded, this also always applies to the personal liability of its employees.

The statutory rights of the Client remain unaffected, insofar as they may not be excluded or reduced.

Claims for damages for which a limitation period is excluded after one year for legal reasons, shall expire 3 years from the Client's receipt of the report or certificate.

The Client undertakes to indemnify Berlin Cert GmbH from claims for damages of any kind, which third parties want to assert against Berlin Cert GmbH due to improper or erroneous use of a certificate or test report by the Client.

6. Confidentiality

Berlin Cert GmbH and its employees are obliged to maintain confidentiality regarding all facts they become aware of via the contractual order. Transcripts (copies) may be created for Berlin Cert GmbH's files of written documents, drawings, plans, etc., which have been submitted to Berlin Cert GmbH for inspection, and which are relevant for implementing the contractual order. Berlin Cert GmbH may make transcripts for its files of written documents that have been submitted for inspection, and which are relevant for carrying out the contractual order.

Expressly exempted from the obligation to maintain confidentiality are statements of information in the context of monitoring activities conducted by accreditation organizations commissioned by Berlin Cert GmbH (e.g. ZLG, ZLS or DAkkS), which do not require further approval by the Client.

Without authorisation, Berlin Cert GmbH, its employees, and third parties it commissions, may not disclose and exploit business and operational conditions and technical content they come to know in the course of their work.

7. Intellectual property rights

Unless otherwise contractually agreed, notwithstanding the terms of the Berlin Cert GmbH contractual order, all intellectual property rights to the expert reports, test results, calculations, illustrations, etc. prepared by Berlin Cert GmbH remain with Berlin Cert GmbH.

8. Testing regulations

8.1. Prerequisite

The Client, for example, a manufacturer of medical devices, its authorized importer or distributor, commissions Berlin Cert GmbH to conduct a test. The commissioning proceeds via a contractual agreement between the Client and Berlin Cert GmbH.

8.2. Service periods / product testing dates

Until final conclusion of the contract, Berlin Cert GmbH's quotes, especially with regard to implementation, prices, and deadlines are subject to change and are not binding, unless they are expressly designated as "binding". The dates and deadlines in the quote will only apply if the contractual order is confirmed by the Client within 5 business days, and the unit to be tested is received with all necessary documents within 10 business days following receipt by Berlin Cert GmbH. Berlin Cert GmbH will provide the Client with confirmation it has received all required documents and of the anticipated date of performance. Should one of the above two conditions not take place within the specified time periods at Berlin Cert GmbH, with confirmation of receipt Berlin Cert GmbH will inform the Client of the start date and expected date of the test order completion.

8.3. Testing location

The tests will generally be carried out in Berlin Cert GmbH's laboratories. Depending on the product and the type of testing, other test sites may be selected if there is assurance that the test environment will not affect the test results. The decision as to test site selection will be at Berlin Cert GmbH's discretion. Checks may also be carried out by external, subcontracted laboratories, if the Client has consented to this.

8.4. Subcontractors

Subcontracted laboratories may come into consideration if they are recognised for the relevant tests by competent accrediting organizations, and have adequately verified this to Berlin Cert GmbH's satisfaction. The commissioning of external test laboratories may be rescinded by Berlin Cert GmbH if the presence of important requirements is no longer ensured, or if Berlin Cert GmbH's complaints regarding the testing laboratory have not been remedied in good time.

8.5. Testing by the Client

Testing may also be carried out by one of the Client's employees under the supervision of a Berlin Cert GmbH expert or testing engineer. In this case the Client undertakes to indemnify Berlin Cert GmbH from liabilities for damages in the event that a Client employee intentionally or negligently commits a breach of obligation. This indemnification obligation also includes judicial and extrajudicial costs.

8.6. Product testing procedure

Upon conclusion of the contract, the Client will submit to Berlin Cert GmbH the test sample or samples free of charge, together with the technical documentation (by agreement) that is necessary to conduct the testing. If more samples are required for the testing, Berlin Cert GmbH may request these free of charge.

The sample will be examined on the basis of legal statutes and regulations, or in accordance with a test program that has been agreed upon between the Client and Berlin Cert GmbH.

If the Client requests labelling certification, after consultation with the Client Berlin Cert GmbH will conduct a manufacturing facility inspection, during which production, assembly, testing equipment, and measures will be reviewed, to ensure continued production quality compliance of series products in relation to the prototype.

The Client will receive written notification once the testing procedure has been completed. The Client will receive a defect report if defects arise. On special request, a short report, a certificate, or a complete report may be prepared for the Client for a surcharge. As part of the certification process, the test report will be submitted to the certification body along with attendant technical documentation.

A test carried out with a positive final report does not relieve the Client of its legal product liability. If no defects are detected, joint liability will only apply for Berlin Cert GmbH if gross negligence during testing can be proven.

8.7. Risk / disposal of testing samples

The contractual partner will provide Berlin Cert GmbH with the test sample at its own expense and risk. Upon request the contractual partner will retrieve the test sample from Berlin Cert GmbH at its own expense and risk.

Shipment will be at our best discretion. The test sample will be carefully packaged. Any damages or breakage that occur during transport are not attributable to Berlin Cert GmbH. The contractual partner must communicate complaints due to transport damage directly to the transport company within the specified deadlines. The acquisition of transport and other insurance is the contractual partner's responsibility.

The contractual partner is obliged to dispose of remaining electronic waste, the test sample, and accessories and packaging in need of disposal at its own expense. If the contractual partner does not comply with its retrieval obligation, Berlin Cert GmbH shall be entitled to send the test sample to the contractual partner at the latter's expense and risk. The costs of sending test samples will be borne by the Client.

If the product tests were carried out as part of a certification process, Berlin Cert GmbH is to be provided with detailed documentation regarding the test sample, from which all relevant aspects of the prototype can be determined. If this documentation is not sufficient, Berlin Cert GmbH will establish whether a reference sample is to be kept by Berlin Cert GmbH, or if a marked and sealed reference sample is to be kept by the certificate holder.

A reference sample stored by the certificate holder must be submitted to Berlin Cert GmbH upon request free of charge on short notice. If the certificate holder is not able to provide the reference sample on short notice, the certificate will become invalid, and any liability claim based on the certification for property or pecuniary damages by the certificate holder against Berlin Cert GmbH will be void.

Documentation and/or reference samples must be kept for at least 10 years past expiry of the certificate's validity. Longer retention periods based on legal regulations are reserved.

Berlin Cert GmbH is not liable for the loss of test and reference samples, nor for damage to the test samples via testing, burglary, theft, water, fire, or transport. Berlin Cert GmbH is however responsible for exercising reasonable care, as per what it would normally exercise for its own similar affairs.

9. Certification

9.1. General

Only those test reports can be made the basis of evaluations in the context of certifications, which satisfy the relevance requirements.

Test reports that are intended to form the basis of certification may not be older than 1 year at the time of certification, and must comply with the generally accepted technology standards at the time of certification.

The test samples in question must be clearly identifiable, and correspondence with the product to be evaluated must be capable of verification.

Granting of a certificate does not relieve the certificate holder of its legal product liability. Berlin Cert GmbH publishes a list of certified products for the information of supervisory authorities and consumers. This requires no special consent from the certificate holder. Furthermore, as an appointed authority Berlin Cert GmbH may forward relevant information concerning EC prototype tests or EC tests with the necessary information, as well as regarding issued or withdrawn certificates and their amendments, to other "appointed authorities" and the competent government authorities, without the certificate holder's consent. Only Berlin Cert GmbH can transfer a certificate to a third party.

9.2. The certificate holder's obligations resulting from certifications

When applying for certificates the Client must declare to Berlin Cert GmbH that it has not submitted the same request with another authority. The certificate holder is obliged to observe the instructions indicated on the certificate, along with any restrictions or limitations.

The certificate holder is required to archive certificates, documents, or reference samples that have been submitted to it for retention within the framework of conformity assessment procedures or labelling certification procedures for the duration of the statutory retention periods, but at least for 10 years past expiry of the certificate's validity, and to provide the Berlin Cert GmbH certification authority with them upon request.

The certificate holder is obliged to continuously monitor the production of the certified products in accordance with the approved testing sample. The certificate holder shall immediately notify the Berlin Cert GmbH certification authority of changes it has made to the product in relation to the approved version, as based on the testing sample.

Additional approval will depend on verification provided by the manufacturer as to compliance with the safety regulations, or on evaluations from additional tests conducted by the Berlin Cert GmbH certification authority.

9.3 Labelling certifications for test labelling conducted by Berlin Cert GmbH
Labelling certifications may only be issued if regular manufacturing facilities inspections are carried out in conjunction with a type test, which result in determining that the presented prototype is of the same product quality. The Berlin Cert GmbH certification authority can prepare a secondary certificate or a certificate extension for identical products that have labelling certification, but which are to be distributed under a different name or a different designation type.

Berlin Cert GmbH carries out regular inspections of production and testing facilities in order to ensure and maintain consistent product quality for products that have been granted labelling certification. Moreover, Berlin Cert GmbH may inspect products, production facilities, and storage areas (including of the importer or authorized representative) associated with the labelling certification, at any time and without prior notification. It can avail itself of the relevant products for inspection checks, and perform inspections of production facilities and storage areas free of charge. The inspection checks can also be appropriately carried out by authorities that Berlin Cert GmbH has authorized. The costs incurred by the certificate holder are governed by the list of fees. For labelling certifications the certificate holder must inform the Berlin Cert GmbH certification authority in good time of relocations of production facilities, or of the intended transfer of its company to another company or to another company owner. The certificate holder must record and archive complaints pertaining to its certified product. On request of the Berlin Cert GmbH certification authority, it must immediately provide these documents free of charge, and provide information on measures taken to effect remedies for existing complaints. If subsequently serious safety deficiencies become evident for products that have been certified by Berlin Cert GmbH, the certificate holder is obliged to withdraw them without delay, and to take appropriate measures to minimize damage in the market. In any case market distribution of the products must cease immediately, and the Berlin Cert GmbH certification authority must be informed. The certificate holder may only forward test reports and the like in full text form, indicating the date of issue. Publication or reproduction requires the prior written consent of Berlin Cert GmbH.

9.6. Rights of the certificate holder resulting from certifications
The certificate holder is entitled to label its products in accordance with the manner described in the certificate, to make use of it in printed matter or other product-related matter, and to draw attention to the issuance of the certificate for advertising purposes. This permission only applies to the period of validity stated in the certificate, but not if the certificate has become void (e.g. due to product changes), or has been declared invalid by the Berlin Cert GmbH certification authority. The labelling certification only applies to the fully certified product. When labelling it must be ensured that no error is made in terms of the kind of testing label certification that has been granted. Berlin Cert GmbH provides reproduction templates for the testing label to be used.

In general the certification regulations System (MU_002) and Product (MU_007) apply.

10. Complaints procedure

The Client may file a written complaint if it is not satisfied with the services provided by Berlin Cert GmbH. The Client, along with Berlin Cert GmbH's management and QMB will be notified immediately upon receipt of the complaint, and kept informed throughout the process. Handling of complaints is monitored via the QMB or a grievance committee, and the complaint will only be concluded in agreement with the customer, who will be duly informed.

11. Privacy policy

Berlin Cert GmbH processes data that has become known to it via the business relationship in accordance with the German Federal Data Protection Act, and is entitled to process the data regarding the initiator of the order that has been obtained in the course of a business relationship, be it as received from the initiator of the order, or be it as received from third parties, within the meaning of the German Federal Data Protection Act.

12. Assignment

The Parties may assign rights and obligations under the contract fully or partially with the prior written consent of the other Party.

13. VAT Internal Market Act

Intra-Community trade in goods (VATIdent.no. DE 162977933) from 1.1.93.

13.1.

The recipient assures the accuracy of the entries for its name, address, and VATIdent.no., which it will communicate immediately and without being prompted, insofar as it has not already done so. It warrants that it will notify both Berlin Cert GmbH, as well as the competent domestic tax authority of any changes to its address and Ident.no., without delay. If tax is payable on a delivery due to defects in the details of name, address, or VATIdent.no., the recipient will reimburse Berlin Cert GmbH for the tax that must be paid.

13.2. If there is a double taxation - purchase tax in recipient's country, VAT in Germany - the recipient will reimburse Berlin Cert GmbH for the overpaid tax.

14. Place of fulfilment and jurisdiction

The place of fulfilment and jurisdiction for both parties is 10587 Berlin, Germany. This exclusive jurisdiction also applies to all current and future claims arising from the business relationship, unless the Party intending to pursue legal actions has moved its domicile or habitual residence outside the valid territory of German law, or unless this is not known at the time of the legal action. The same applies in the event that claims are asserted in the course of a dunning procedure (§§ 688 et seq. ZPO/German Code of Civil Procedure). It is agreed that those rights will exclusively apply as are valid in the Federal Republic of Germany. Application of the UN Sales Convention (CISG) is excluded.

15. Payment conditions and prices

Unless otherwise agreed in writing (e.g. pricing, fixed price), the published rates of Berlin Cert GmbH valid at the time of order confirmation will apply for the invoicing of

services. If due to reasons Berlin Cert GmbH's contractual partner is responsible for the testing extends over a period of more than four months, whereby there has been an interim price increase, from the fifth month the new prices will apply, and given subsequent price increases the then prevailing prices will apply at the time of their entry into force. Advance payments may be requested, and partial invoices may be submitted. Partial invoices need not be designated as such; the receipt of an invoice does not mean that Berlin Cert GmbH has therefore fully settled the contractual order.

The invoice amount is payable within 2 weeks after invoicing, but is payable no later than by the specified date. Given late payment, interest on arrears for the outstanding amount of 2% above EURIBOR will be invoiced for the period between the due date of the payment and receipt of payment.

Bills of exchange, cheques, and payment orders are accepted by agreement only, and then only as conditional payment. They will be considered as payment when they are redeemed. Standard bank charges shall be borne by the Client. Offsetting payment against, or withholding payment on account of a counterclaim is excluded, unless the counterclaim is undisputed or legally binding.

If the Client is late paying the invoice, Berlin Cert GmbH can withdraw from the contract or demand compensation for damages instead of performance. Subject to claims for further damages, in the event of default payment Berlin Cert GmbH is entitled to interest on arrears at the statutory rate.

VAT will be separately charged in the amount valid at the time of invoicing, in addition to the service prices.

Complaints regarding invoices must be communicated and justified in writing within a limitation period of 14 days after receipt of the invoice.

16. Subsidiary agreements

Subsidiary agreements, amendments, or supplements to these general terms and conditions or contracts require Berlin Cert GmbH's written confirmation before coming into force.

17. Final provisions

In that event that any provision of these general terms and conditions is invalid or unenforceable, or if these general terms and conditions contain gaps, the validity of the remaining provisions shall not be affected. Instead of the invalid or unenforceable provisions, a valid or enforceable provision shall be deemed agreed upon which comes closest to the sense and purpose of the invalid or unenforceable provision.

Status: see revision on page 1

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